

REMARKS

Favorable reconsideration and allowance of this application are requested.

By way of the amendment instructions above, each of the pending independent claims has been amended so as to emphasize that the at least one traction-resistant fibre form substantially radially oriented continuous windings which run substantially along *geodetic lines* about the lower and upper surfaces of the flattened body. Support for such amendment may be found in the specification at page 3, lines 13-33, especially at lines 24-26 thereof.

Claims 21 and 22 are new. In this regard, claim 21 is in independent form and is substantively similar to the amended version of claim 1 presented above, in addition to requiring that the flexible nucleus has a modulus of at most 50 MPa, support for which is present at page 1, line 33 of the specification.

Claim 22 depends from claim 1 or 21 and requires that the continuous windings across the lower and upper surfaces of the flattened body are substantially radially oriented such that at least 50% of the windings follow a path whose smallest distance to a center of gravity of the lower and upper surfaces is at most equal to 30% of a largest dimension of the lower and upper surfaces. Support for new claim 22 may be found at page 3, lines 14-17 of the specification.

Therefore, following entry of this amendment, claims 1-11 and 13-22 will be pending herein for which favorable action on the merits is requested.

The only issue remaining to be resolved in this application is the assertion that claims 1-11 and 13-20 are "obvious" and hence unpatentable under 35 USC §103(a) based on Trieu (USP 6,733,531) in view of Reiley et al (USP 6,066,154). Applicants suggest that the claims presented above unquestionably define patentable subject matter over such applied references.

Trieu, like the present application, is directed to an intervertebral disc. Such discs comprise a nucleus. It is really at this juncture that any perceived similarities between the present invention and Trieu end.

Specifically, the nucleus of the intervertebral disc of the present invention is:

- surrounded by a fiber,
- the fiber is wound in a special pattern: i.e., it is first of all wound around each of the upper and lateral surfaces forming substantially radially oriented continuous windings about the lower and upper surfaces of the flattened body,
- the windings substantially run according to geodetic lines, and
- the fiber has a length of at least 10 times the circumference of the nucleus.

In Trieu the nucleus is surrounded at the lateral surface by a mesh. So in Trieu no "fiber" is wound *around* the nucleus.

In essence, the Examiner appears to assert that since Reiley et al seems to equate mesh supports with "windings", then one of ordinary skill in this art would have obviously substituted such "windings" for the mesh of Trieu '531. Applicants emphatically disagree with such an analysis.

Factually, it should be noted that the manner in which the term "winding" is included within the same statement of terms "embedded" and "laminated" at column 13, line 9 of Reiley et al, which terms are separated by commas from the term "mesh 170" makes it clear that all terms "embedded", "laminated" and "winding" are meant to refer to the "mesh 170". Thus, with respect to the term "winding", Reiley et al notes that it is the mesh 170 that may be wound around the neck 172. Additionally or alternatively (i.e., and/or) the mesh 170 may be "embedded or laminated". Thus, the conclusion reached by the Examiner is not supported by Reiley et al in the manner postulated.

Thus, the paragraph cited by the Examiner does not suggest that a mesh is equivalent to a wound fiber at all. As noted above, "winding" in Reiley refers only to the manner in which the mesh per se is positioned with respect to the neck 172.

Even if "winding" in Reiley does not refer to mesh, Reiley is not combinable with Trieu. If "winding" in Reiley does not refer to mesh, than it is unclear to what winding refers. The paragraph in Reiley does not specifically refer to the winding of a fiber, since the term fiber is missing. So if "winding" does not refer to mesh it may refer to anything that may be wound.

Even if Reiley is directed to the winding of a fiber, this does not mean that Reiley may be combined with Trieu, because Trieu and Reiley relate to non-analogous structures wherein the structural parts in question have completely different functions.

Reiley is directed to a balloon, to be inserted in a broken bone, to bring the bone segments in place. By the balloon only a moderate pressure may be applied (i.e., see the abstract). Trieu on the other hand is directed to an intervertebral disc, which is a completely different art area, with a completely different function and a completely different set of problems to solve. It comprises a nucleus of material that must be strong enough to withstand the very high pressures that may be applied in the spine of a persons body.

So even if it was true that Reiley is directed to a winding of a fiber, this will not give any hint or motivation whatsoever to a skilled person to replace the mesh of Trieu by the winding of a fiber.

The mesh in column 13 of Reiley is used to provide a neck in a balloon so it is capable of compacting a cancellous bone in a proximal humerus. The disc of Trieu on the contrary is used as an intervertebral disc and the mesh around the disc has a completely different function. A disc is *not* a balloon. The mesh around the disc is *not*

present to provide a neck. There is therefore absolutely no reason for the skilled person to apply a method of making a neck in the balloon of Reiley to the intervertebral disc of Trieu.

The determination of whether or not a reference is from non-analogous art, and hence whether such art is available for use pursuant to an obviousness inquiry under 35 USC §103(a), is twofold. First, a determination must be made whether the art is from the same field of endeavor, regardless of the problem addressed, and secondly if the art is not within the same field of endeavor, a determination must be made whether it is still reasonably pertinent to the particular problem to be solved.¹

In this particular situation, it seems quite clear that Reiley is not from the same field of endeavor as the present invention. Specifically, as noted above, Reiley is concerned with providing a neck in a balloon, to be able to use the balloon to compact a cancellous bone in a proximal humerus, which is of course clearly not the same endeavor as providing an intervertebral disc having the structural and functional attributes required of the same. Moreover, as also noted above, the problem confronted by Reiley and the present applicants are quite different.

Therefore, Reiley is not analogous art to the presently claimed invention and, as such, is not properly combinable with Trieu to support a rejection under 35 USC §103(a) as it is not a part of the "content" of prior art of which the ordinarily skilled person in this particular technical field would be cognizant.

Finally, even assuming for the moment that Trieu and Reiley were combined, and assuming that Reiley does indeed contemplate winding a fiber (both being assumptions that the applicant categorically reject), then this would not result in the disc of the present application. Specifically, there would be no teaching or guidance in either Trieu or Reiley that the fiber be wound in a special pattern substantially according to geodetic

lines and/or that the fiber has a length of at least 10 times the circumference of the nucleus.

To summarize:

- Reiley does not disclose winding of a fiber,
- the skilled person is not motivated at all to employ the structure used at the neck of the balloon according to Reiley and apply it to the disc of Trieu, and
- even if the mesh of Trieu were replaced by a winding of a fiber, there is still no teaching or suggestion of winding the fiber in the special pattern required by the claims pending herein, i.e., substantially according to geodetic lines.

Because of the windings of the fiber surrounding the nucleus of the disc of the present invention protrusions of the material of the nucleus are prevented. This function is contrary to the disc of Trieu, where large openings between meshes make the disc prone to protrusions. Protrusions are unacceptable, since after protrusions occur, the disc must be replaced. Applicants also refer to Fig 2 and page 6 lines 25 and below, where it is explained that the disc of the present invention is able to withstand forces up to 700 kg. In Trieu on the contrary only forces up to 700 Newtons are reported (column 11, lines 55-60), which is only about 10% of the forces that may be experienced according to the present application.

A further advantage of the disc according to the present invention is that because of the very low tendency for protrusions to occur, it is even possible to use nucleus material with a low stiffness, e.g., on the order of a modulus of at most 50 MPa as defined in new claim 21. This low stiffness nucleus material gives a much better

¹ *Wang Laboratories Inc. v. Toshiba Corp.*, 24 USPQ2d 1767, 1773 (Fed. Cir. 1993).

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resilience to the nucleus, which is important for an intervertebral disc, because it gives more comfort to a patient.

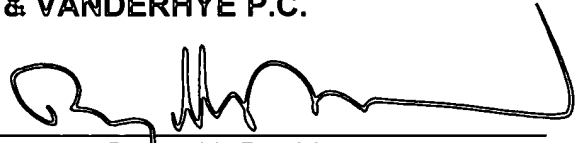
Therefore, in view of the amendments and remarks above, all claims pending in this application are believed to be allowable over the art of record. Such favorable action is therefore solicited.

Should any small matters remain outstanding, the Examiner is encouraged to telephone the Applicants' undersigned attorney so that the same may be resolved without the need for an additional written action and reply.

Respectfully submitted,

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